

REMARKS

Claims 1-13 currently appear in this application. The Office Action of May 20, 2005, has been carefully studied. These claims define novel and unobvious subject matter under §§ 102 and 103 of 35 U.S.C., and therefore should be allowed. Applicants respectfully request favorable reconsideration, entry of the present amendment, and formal allowance of the claims.

Restriction Requirement

It is noted that the Restriction Requirement is maintained, and that claims 1-3 and 6-11 were examined to the extend that they read on the elected subject matter of group I (i.e. the animal to be treated suffers from an autoimmune disease which causes secretions and eruptions via the calcium cascade).

Allowable Subject Matter

It is noted that a method of inhibiting the calcium cascade comprising administering to an animal in need of treatment for the bulbous form of impetigo an effective amount of a mixture of zinc and copper metal ions to block the calcium cascade is deemed to be allowable.

Rejections under 35 U.S.C. §112

Claims 1-3 and 6-11 are rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for metal ions that have antimicrobial activity, which are administered to an animal that has a condition with an underlying or concomitant microbial etiology, is said not to reasonably provide enablement for the full scope of the claims.

This rejection is respectfully traversed. Reference has been made in the specification at paragraph [0017] to the present inventor's patent No. 6,414,033, which has been incorporated by reference in the entirety. This patent describes use of the Teorell-Meyer gradient to administer bioactive agents from one bodily compartment to another. This is particularly effective for ionized bioactive agents. This technique of administration has been demonstrated to be effective for delivering bioactive agents to the body.

The present invention is directed to administer pharmaceutically effective metal ions and combinations of ions to swamp the calcium ions naturally occurring in the body so as to block the calcium cascade, thereby inhibiting the formation of histamine.

Paragraphs [0020] through [0029] describe the calcium cascade and the effect it has on the body. Paragraphs

[0031] through [0033] describe how administration of therapeutic doses of metal ions can be used to block the production of histamine triggered by the calcium cascade. Paragraphs [0034] through [0045] describe how these metal ions are administered using the Teorell-Meyer gradient.

It is respectfully submitted that one skilled in the art, reading U.S. Patent No. 6,414,033 and the passages from the specification as filed, would be able to administer metal ions to block the calcium cascade without undue experimentation.

Art Rejections

Claims 1-3 and 10 are rejected under 35 U.S.C. §103(a) as being unpatentable over Kashirina in view of Mandell et al.

This rejection is respectfully traversed. First of all, the zinc-synctomycin paste is used by Kashirina is used in conjunction with a solution of salicylic alcohol, vodka, boron alcohol, or camphor alcohol. It should also be noted that, besides the local treatment, the patients received individual general therapy, including calcium gluconate, diphenhydramine hydrochloride, vitamins, etc. Diphenhydramine hydrochloride is a known anti-histamine. It is not clear from Kashirina if the diphenhydramine was the effective agent, the zinc ions, or the synctomycin.

Mandell et al. support the action of the synctomycin as effective agent in treating impetigo, as it is believed that impetigo is caused by Group A *Streptococcus*, either alone or mixed with *Staphylococcus aureus*. It is respectfully submitted that this combination of references would lead one skilled in the art to treat impetigo with an antibiotic, such as synctomycin. The zinc ion is merely one form of synctomycin, and may or may not have anything to do with successful treatment of impetigo.

Neither Mandell et al. or Kasharina discloses or suggests administering a bioactive agent using the Teorell-Meyer gradient.

In view of the above, it is respectfully submitted that the claims are now in condition for allowance, and favorable action thereon is earnestly solicited.

Respectfully submitted,

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